'DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 4 1996

Dr. Patrick Rudelsheim
Registration Manager
Plant Genetic Systems, N.V. (PGS)
Jozef Plateaustraat 22
B-9000 Gent
Belgium

Dear Dr. Rudelsheim:

This is in regard to PGS's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified oilseed rape, specifically transformation events B91-4, B93-101, and B94-2. According to PGS, transformation event B91-4 oilseed rape is modified to express the *neo* (*kanR*) gene from a *Tn5* carrying plasmid from *Escherichia coli*, the *bar* gene from *Streptomyces hygroscopicus*, and the *barnase* gene from *Bacillus amyloliquefaciens*. These genes encode the respective proteins for aminoglycoside resistance (NPTII), glufosinate herbicide tolerance (PAT), and male sterility inducing RNase (barnase; a specific RNase). Lines containing transformation events B93-101 and B94-2 are modified to express *neo* and *bar*, as above, as well as the *barstar* gene from *B. amyloliquefaciens*. The latter gene encodes a specific RNase inhibitor protein (barstar), thereby making these oilseed rape lines fertility restorers to the male sterile rape line (B91-4) when cross-pollinated (*i.e.*, pollination control system), leading to the development of 100% hybrid seed for commercial purposes.

In November of 1992, PGS met with FDA to discuss their proposed safety and nutritional assessment of oilseed rape containing the aforementioned transformation events. As part of bringing PGS's consultation regarding these products to closure, PGS submitted a summary of the assessments of oilseed rape containing transformation events B91-4 and B93-101 on July 6, 1995. A second submission for transformation event B94-2 was submitted by PGS on October 23, 1995.

These communications informed FDA of the steps taken by PGS to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment that you have conducted, it is our understanding that PGS has concluded that oilseed rape oil, honey (nectar) and cake (meal), derived from the hybrid seed, are not materially different in composition, safety, and other relevant parameters from oilseed rape oil, honey (nectar) and cake (meal) presently on the market, and that genetically modified oilseed rape does not raise issues that would require

premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0032. This file will be maintained in the Office of Premarket Approval.

Based on the information PGS has presented, we have no further questions concerning oil, honey (nectar) and cake (meal) from hybrid seed derived from transformation events B91-4, B93-101, and B94-2 at this time. However, as you are aware, it is PGS's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247
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